

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

BIG TIME VAPES, INC. and UNITED	§	
STATES VAPING ASSOCIATION,	§	
INC.,	§	
	§	
<i>Plaintiffs,</i>	§	
	§	Civil Case No. 1:19-cv-531-LG-JCG
v.	§	
	§	
FOOD AND DRUG	§	ORAL ARGUMENT REQUESTED
ADMINISTRATION; NORMAN E.	§	
“NED” SHARPLESS, M.D., in his	§	
official capacity as Acting Commissioner	§	
of Food and Drugs; and ALEX M.	§	
AZAR, II, in his official capacity as	§	
Secretary of Health and Human Services,	§	
	§	
<i>Defendants.</i>	§	

PLAINTIFFS’ MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs Big Time Vapes, Inc., an e-liquid “manufacturer” and retail vapor shop located in Picayune, Mississippi, and United States Vaping Association, Inc., a trade association representing small businesses in the United States vapor industry, hereby move for a preliminary injunction pursuant to Federal Rule of Civil Procedure 65.

By this motion, Plaintiffs seek an order preliminarily enjoining Defendants from taking any regulatory or enforcement action against Plaintiffs (Big Time Vapes, Inc., and the USVA’s members) arising under, or by reason of, the Defendants’ purported authority under the Tobacco Control Act of 2009 to “deem” “tobacco products” to be subject to the TCA.

Plaintiffs satisfy all the elements of injunctive relief, as explained in detail in the accompanying memorandum. Plaintiffs raise a single argument in this motion: that Section

387a(b) of the TCA violates the separation of powers because it purports to transfer legislative power to the Secretary of Health and Human Services. The TCA authorizes the Secretary to “deem” any tobacco products to be subject to the TCA—or not to deem them and leave them unregulated—in his or her absolute discretion. Congress provided no policy to guide the Secretary’s exercise of deeming discretion in that the statute contains no standards, no parameters, and no hints as to when or why a given tobacco product should be regulated under the TCA. While the Supreme Court has upheld broad delegations, it has never upheld a statute like Section 387a(b), and, in fact, it has twice invalidated federal statutes that, like the TCA, delegated legislative power to the executive by providing *no* standard or policy. Therefore, it is substantially likely that Plaintiffs will prevail on the merits.

Plaintiffs are threatened with imminent irreparable harm in the absence of preliminary relief for several reasons, including the complete destruction of their businesses, loss of employment, lost investments, and lost income. Several of the business owners will be driven to personal bankruptcy. Economic damages are irreparable in this case because the federal government Defendants are immune from damages. Therefore, without an injunction, Plaintiffs will suffer catastrophic financial harm, with no hope of ever securing compensation, even if they were to continue litigating and prevail on the merits. The regulations will also wholly destroy Plaintiffs’ businesses if they become effective, which also constitutes irreparable harm. These damages are impending based on two aspects of the Defendants’ regulation under the TCA. First, the Defendants announced a revised enforcement policy will be released any day now, to be effective approximately 30 days after announcement, that will effectively remove flavored e-cigarette products (aside from tobacco flavors) from the market. If this policy becomes effective, it will destroy Plaintiffs’ businesses and investments. Second, the PMTA requirement applied to

Plaintiffs' products presents an insurmountable obstacle that will nonetheless require Plaintiffs to incur substantial compliance costs in an attempt to complete a satisfactory PMTA, submit it by the deadline, and remain viable. But even if they were able to submit a single PMTA, they would have to remove the vast majority of their other products from the market, causing substantial lost business and likely preventing their survival anyway.

The public interest also favors the injunction, as protecting constitutional interests is always in the public interest, and the government has no legitimate claim to exercising regulatory power that is inconsonant with the separation of powers. Additionally, the Defendants themselves have recognized the public interest is served by keeping Plaintiffs' products on the market. To the extent the Defendants *now* propose that the public interest requires a different result, their assertions as to the prioritization of various interests is entitled to little weight where *their authority* to determine such prioritization is the very question at issue in this case. Finally, the balance of harms clearly favors granting injunctive relief. Whereas Plaintiffs will be severely and irreparably—even permanently—harmed if these regulatory actions are not enjoined, granting the injunction until a final merits decision would not materially harm any interest of Defendants.

Plaintiffs contemporaneously file exhibits, an index of exhibits, and a memorandum in support of this motion. Plaintiffs respectfully request oral argument.

Respectfully submitted,

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*Motion for admission *pro hac vice* forthcoming.

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that the foregoing motion for preliminary injunction, including all exhibits and the index of exhibits, will be served by personal delivery upon the Defendants listed below as soon as possible. Further, Plaintiffs' counsel Jerad Najvar emailed Mr. Eric Beckenhauer, an attorney with the Federal Programs Branch of the U.S. Department of Justice, and who currently represents Defendants in other Deeming Rule litigation, on October 3 to notify him of this forthcoming motion. Mr. Najvar and Mr. Beckenhauer have been in periodic communication by email since that date. A courtesy copy of all documents will be emailed to Mr. Beckenhauer immediately upon filing of same.

By personal delivery:

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

Norman E. Sharpless, M.D., in his official
capacity as
Acting Commissioner for Food and Drugs
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

Alex M. Azar, II in his official capacity as
Secretary of U.S. Department of Health and
Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Courtesy copy by email on October 10, 2019:

Eric B. Beckenhauer
Assistant Director
U.S. Department of Justice
Civil Division, Federal Programs Branch
eric.beckenhauer@usdoj.gov

/s/ Spencer M. Ritchie
SPENCER M. RITCHIE